

WHAT IS CLAIMED IS:

1 1. A prosthetic heart valve resistant to tissue overgrowth following
2 implantation of said prosthetic heart valve into a host, said heart valve comprising a
3 sewing ring, and a housing component enclosing a valve component, wherein a member
4 selected from said sewing ring, said housing component, said valve component and
5 combinations thereof comprises at least one biologically active material in an amount
6 sufficient to prevent tissue overgrowth.

1 2. The heart valve according to claim 1, wherein said sewing ring
2 comprises said at least one biologically active material.

1 3. The heart valve according to claim 1, wherein said sewing ring
2 comprises a polymeric material.

1 4. The heart valve according to claim 3, wherein said polymeric
2 material comprises a member selected from plastics, rubbers and combinations thereof.

1 5. The heart valve according to claim 3, wherein said polymeric
2 material is a fabric.

1 6. The heart valve according to claim 5, wherein said fabric
2 comprises a material that is a member selected from thermoplastic polyurethanes TPUs,
3 nylons, polypropylene, polytetrafluoroethylene, polyesters, nylon polymers, block
4 copolymers of a polyether polymer and a polyester polymer, and block copolymers of a
5 polyether polyol and one selected from the group consisting of polyamides, polyimides,
6 polyolefins, synthetic hydrocarbon elastomers, and natural rubber.

1 7. The heart valve according to claim 5, wherein said polyester is
2 polyethylene terephthalate (PET).

1 8. The heart valve according to claim 5, wherein said nylon is a
2 member selected from nylon-11, nylon-12 and combinations thereof.

1 9. The heart valve according to claim 5 wherein said polyolefin is a
2 member selected from polyethylenes (PE) and polypropylenes (PP).

1 **10.** The heart valve according to claim 5, wherein said fabric is a
2 member selected from a weft knit with a velour, a weft knit without a velour, a warp knit
3 with a velour, a warp knit without a velour, a weave structure with a velour, a weave
4 structure without a velour and combinations thereof.

1 **11.** The heart valve according to claim 10, wherein said fabric
2 comprises a combination yarn comprising at least two polymeric components.

1 **12.** The heart valve according to claim 11, wherein said combination
2 yarn comprises polyester wrapped with polypropylene yarn.

1 **13.** The heart valve according to claim 1, wherein said at least one
2 biologically active material is a member selected from antithrombotics,
3 antiinflammatories, corticosteroids, antimicrotubule agents, antisense oligonucleotides,
4 antineoplaastics, antioxidants, antiplatelets, calcium channel blockers, converting enzyme
5 inhibitors, cytokine inhibitors, growth factors, growth factor inhibitors, growth factor
6 sequestering agents, immunosuppressives, tissue factor inhibitor, smooth muscle
7 inhibitors, organoselenium compounds, retinoic acid, retinoid compounds, sulfated
8 proteoglycans, NO, NO precursors and combinations thereof.

1 **14.** The heart valve according to claim 13, wherein said antithrombotic
2 is a member selected from heparin, heparin derivatives, hirudin, hirudin derivatives and
3 combinations thereof.

1 **15.** The heart valve according to claim 13, wherein said corticosteroid
2 is a member selected from dexamethasone, dexamethasone derivatives and combinations
3 thereof.

1 **16.** The heart valve according to claim 13, wherein said
2 antimicrotubule agent is a member selected from taxane, taxane derivatives and
3 combinations thereof.

1 **17.** The heart valve according to claim 13, wherein said antiplatelet
2 agent is an inhibitor of collagen synthesis.

1 **18.** The heart valve according to claim 17, wherein said inhibitor of
2 collagen synthesis is a member selected from halofuginore, halofuginore derivatives,
3 GpII_bIII_a and combinations thereof.

1 **19.** The heart valve according to claim 1, wherein said biologically
2 active material adheres tenaciously, without covalent bonding, to a member selected from
3 said sewing ring, said housing component, said valve component and combinations
4 thereof.

1 **20.** The heart valve according to claim 19, wherein said sewing ring
2 comprises said biologically active material.

1 **21.** The heart valve according to claim 19, wherein said biologically
2 active material is combined with a surfactant.

1 **22.** The heart valve according to claim 21, wherein said surfactant is a
2 member selected from benzalkonium halides and sterylalkonium halides.

1 **23.** The heart valve according to claim 19, wherein said biologically
2 active material comprises a taxane, a taxane derivative and combinations thereof.

1 **24.** The heart valve according to claim 19, further comprising a coating
2 layered over said biologically active material.

1 **25.** The heart valve according to claim 24, wherein said coating is a
2 member selected from bioerodable coatings, hydrogel coatings, thermoreversible
3 coatings, bioresorbable coatings and combinations thereof.

1 **26.** The heart valve according to claim 1, wherein said biologically
2 active material is covalently bonded to a reactive group located on a member selected
3 from said sewing ring, said housing component, said valve component and combinations
4 thereof.

1 **27.** The heart valve according to claim 26, wherein said biologically
2 active material is covalently bound to said sewing ring.

1 **28.** The heart valve according to claim **26**, wherein said reactive group
2 is selected from amine-containing groups, hydroxyl groups, carboxyl groups, carbonyl
3 groups, and combinations thereof.

1 **29.** The heart valve according to claim **28** wherein said amine-
2 containing groups are selected from amino groups, amido groups, urethane groups, urea
3 groups, and combinations thereof.

1 **30.** The heart valve according to claim **29**, wherein said amino groups
2 are selected from the group consisting of primary amino groups, secondary amino groups,
3 and combinations thereof.

1 **31.** The heart valve according to claim **30** wherein said amino groups
2 are derived from a nitrogen-containing gas selected from the group consisting of
3 ammonia, organic amines, nitrous oxide, nitrogen, and combinations thereof.

1 **32.** The heart valve according to claim **31**, wherein said organic amines
2 are selected from methylamine, dimethylamine, ethylamine, diethylamine, n-
3 propylamine, allylamine, isopropylamine, n-butylamine, n-butylmethylamine, n-
4 amylamine, n-hexylamine, 2-ethylhexylamine, ethylenediamine, 1,4-butanediamine, 1,6-
5 hexanediamine, cyclohexylamine, N-methylcyclohexylamine, and ethyleneimine.

1 **33.** The heart valve according to claim **26**, wherein when said substrate
2 is a polymer and said reactive chemical functional groups are affixed to the surface of
3 said substrate by plasma fixation.

1 **34.** The heart valve according to claim **26**, wherein said biologically
2 active material is a taxane, a taxane derivative and combinations thereof.

1 **35.** The heart valve according to claim **26**, further comprising a coating
2 layered over a component that is a member selected from said sewing ring, said housing
3 component, said valve component and combinations thereof.

1 **36.** The heart valve according to claim **35**, wherein said coating is a
2 member selected from bioerodable coatings, hydrogel coatings, thermoreversible
3 coatings, bioresorbable coatings and combinations thereof.

1 **37.** The heart valve according to claim 1, further comprising a
2 microcapsule encapsulating said biologically active material, said microcapsule being
3 incorporated into a component of said heart valve that is a member selected from said
4 sewing ring, said housing component, said valve component and combinations thereof.

1 **38.** The heart valve according to claim 37, further comprising a coating
2 layer.

1 **39.** The heart valve according to claim 38, wherein said coating is
2 layered over said microcapsule.

1 **40.** The heart valve according to claim 38, wherein said microcapsule
2 is embedded in said coating.

1 **41.** The heart valve according to claim 38, wherein said coating is a
2 member selected from bioerodable coatings, hydrogel coatings, thermoreversible
3 coatings, bioresorbable coatings and combinations thereof.

1 **42.** The heart valve according to claim 37, wherein said microcapsules
2 are fabricated from a material that undergoes erosion in said host, thereby providing for
3 controlled release of said encapsulated biologically active material from said
4 microcapsules.

1 **43.** The heart valve according to claim 42, wherein said microcapsules
2 comprise a sodium alginate envelope.

1 **44.** The heart valve according to claim 1, wherein a member selected
2 from said sewing ring, said housing component, said valve component and combinations
3 thereof is at least partially covered with a coating for release of at least one of said
4 biologically active material, the coating comprising a reservoir component comprising
5 said biologically active material.

1 **45.** The heart valve according to claim 44, wherein said coating
2 comprises a member selected from gels, foams, suspensions, microcapsules, solid
3 polymeric supports and fibrous structures.

1 **46.** The heart valve according to claim **46**, wherein said coating
2 comprises a bioresorbable component.

1 **47.** The heart valve according to claim **46**, wherein the bioresorbable
2 component is insoluble in water.

1 **48.** The heart valve according to claim **46**, wherein said bioresorbable
2 component is hydrophobic.

1 **49.** The heart valve according to claim **46**, wherein said bioresorbable
2 component is hydrolytically and/or enzymatically cleavable.

1 **50.** The heart valve according to claim **49**, wherein said bioresorbable
2 component is selected from poly(esters), poly(hydroxy acids), poly(lactones),
3 poly(amides), poly(ester-amides), poly (amino acids), poly(anhydrides),
4 poly(orthoesters), poly(carbonates), poly(phosphazines), poly(phosphoesters),
5 poly(alkylene oxides)poly(thioesters), polysaccharides, proteins and mixtures thereof.

1 **51.** The heart valve according to claim **50**, wherein said bioresorbable
2 component is a poly(hydroxy) acid.

1 **52.** The heart valve according to claim **51**, wherein said poly(hydroxy)
2 acid is formed from a material selected from poly(lactic) acid, poly(glycolic) acid,
3 poly(caproic) acid, poly(butyric) acid, poly(valeric) acid and copolymers and mixtures
4 thereof.

1 **53.** The heart valve according to claim **46**, wherein said bioresorbable
2 component forms an excretable and/or metabolizable fragment.

1 **54.** The heart valve according to claim **45**, wherein said gel is a
2 thermoreversible gel.

1 **55.** The heart valve according to claim **54**, wherein said gel comprises
2 a member selected from pluronics, fibrin sealants, albumin, collagen, gelatin,
3 hydroxypropylmethylcellulose, polyethylene oxide, hyaluronic acid, polysaccharides
4 and combinations thereof.

1 **56.** The heart valve according to claim **45**, wherein said gel comprises
2 a member selected from polyurethane hydrogels and polyurethane-urea hydrogels.

1 **57.** The heart valve according to claim **1**, comprising a first population
2 of bioactive material having a first release rate from said heart valve, and a second
3 bioactive material having a second release rate from said heart valve.

1 **58.** The heart valve according to claim **57**, wherein said first bioactive
2 material and said second bioactive material are the same material.

1 **59.** The heart valve according to claim **57**, wherein said first bioactive
2 material and said second bioactive material are different materials.

1 **60.** The heart valve according to claim **57**, wherein said first bioactive
2 material is encapsulated in a microcapsule and said second bioactive material is admixed
3 in a coating comprising said microcapsule, said coating covering at least a portion of a
4 component that is a member selected from said sewing ring, said housing component,
5 said valve component and combinations thereof.

1 **61.** A method for preventing or reducing tissue overgrowth of a
2 prosthetic heart valve following the implantation of said heart valve into a host, said
3 method comprising:
4 prior to said implantation, incorporating into a component of said heart
5 valve a biologically active agent in an amount sufficient to prevent or retard tissue
6 overgrowth.

1 **62.** A method of treating a patient requiring heart valve replacement,
2 said method comprising:
3 replacing an existing valve with a prosthetic heart valve comprising a
4 biologically active agent in an amount sufficient to prevent or retard tissue overgrowth.